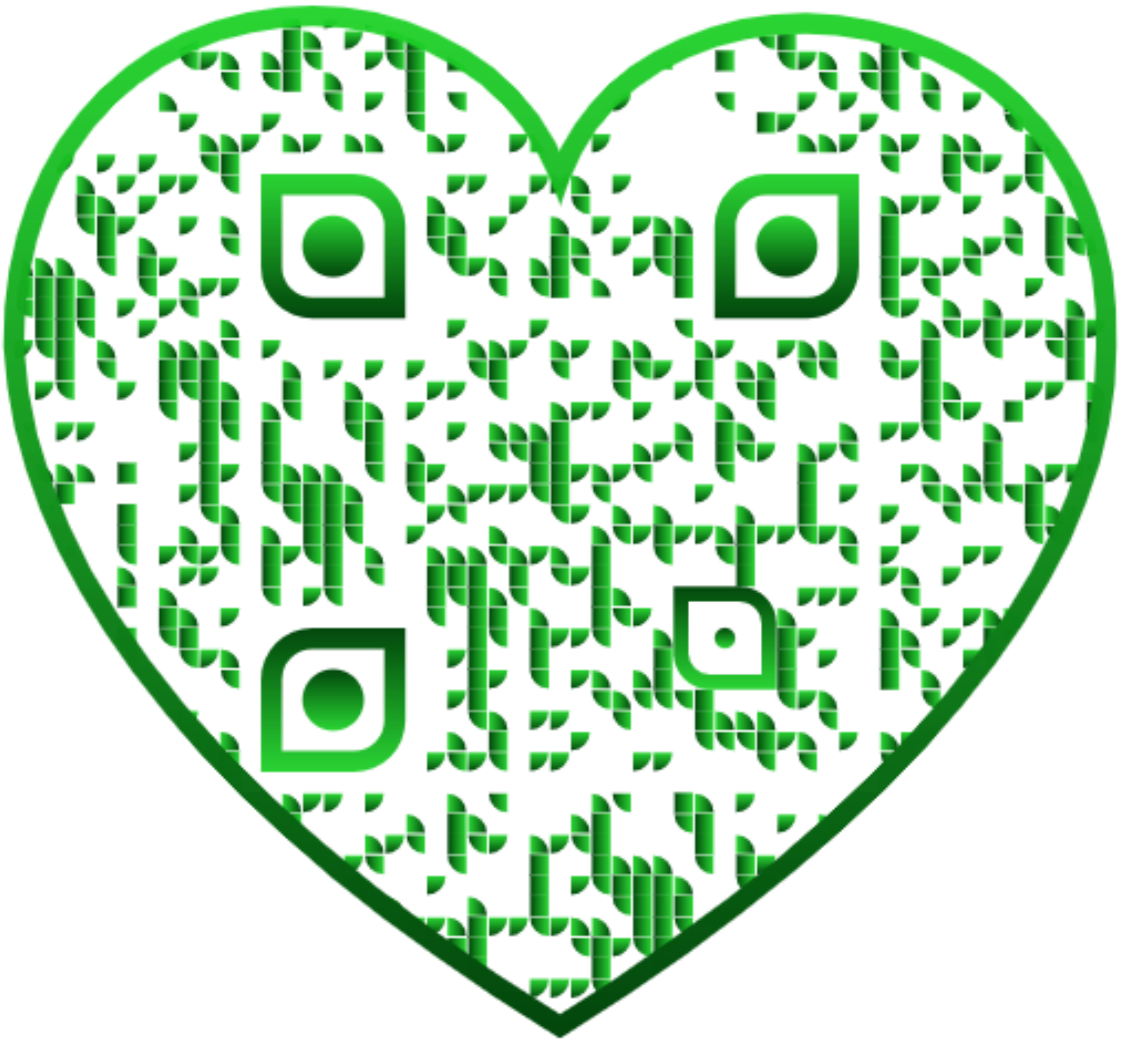
Tablets and Compaction



Introduction

- Among the oral dosage forms tablets of various types are the most common.
- At least 90% of all drugs used to produce systemic effects are administered by the oral route.
- Tablets are defined as:
  - "solid preparations each containing a single dose of one or more active ingredients and obtained by compressing uniform volumes of particles"

- Tablets are used mainly for systemic drug delivery
  - For systemic use the drug must be released from the tablet,
  - Thereafter, be absorbed into the systemic circulation, by which it reaches its site of action.
- Alternatively, tablets can be formulated for local delivery of drugs in the mouth or GIT

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- Tablets are popular for several reasons:
  - Oral route is a convenient and safe way of administration
  - They are unit dose form, provide greatest dose precision and the least content variability.
  - Their cost is lowest of all oral dosage forms.
  - The lightest and most compact of all oral dosage forms.
  - The easiest and cheapest to package and ship of all oral dosage forms.

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- Product identification is potentially the simplest and cheapest,
- Provide the greatest ease of swallowing with the least tendency for " hang - up" above the stomach,
- Important to design special release profile products such as enteric or delayed release products.
- They are better suited to large - scale production than other unit oral forms (with robust and quality-controlled production procedures)
- They have best combined properties of chemical, mechanical & microbiological stability than other unit oral forms.

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- Limitations:
  - Bioavailability of poorly water-soluble or poorly absorbable drugs,
  - Some drugs may cause local irritant effects or cause harm to the GI mucosa,
  - Some drugs resist compression into dense compacts,
  - Special coating is required for drugs with bitter testing, objectionable odor or drugs that are sensitive to oxygen or atmospheric moisture,

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- Quality attributes of tablet:
  - The tablet should include the correct **dose** of the drug,
  - The appearance of the tablet should be elegant and its weight, size and appearance should be **consistent**,
  - The drug should be **released** from the tablet in a controlled and reproducible way,
  - The tablet should be **biocompatible**,

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- Tablet should be of sufficient **mechanical strength** to withstand fracture and erosion during handling,
- Tablet should be chemically, physically and microbiologically **stable**,
- Tablet should be **packed** in a safe manner.

Tablet Compression

- Solid is contained in a **die** and a compressing force is applied to it by means of **punches**
  - The shape of the die governs the cross-sectional shape of the tablet,
  - The distance between the punch tips at the point of maximum compression governs its thickness
  - The conformation of the tablet faces is a reflection of those of the punches

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- The process of tablet compression can be divided into three stages:

Stage 1: Filling

- The lower punch falls within the die,
  - This leaves a cavity into which particulate matter flows under the influence of gravity from a hopper.

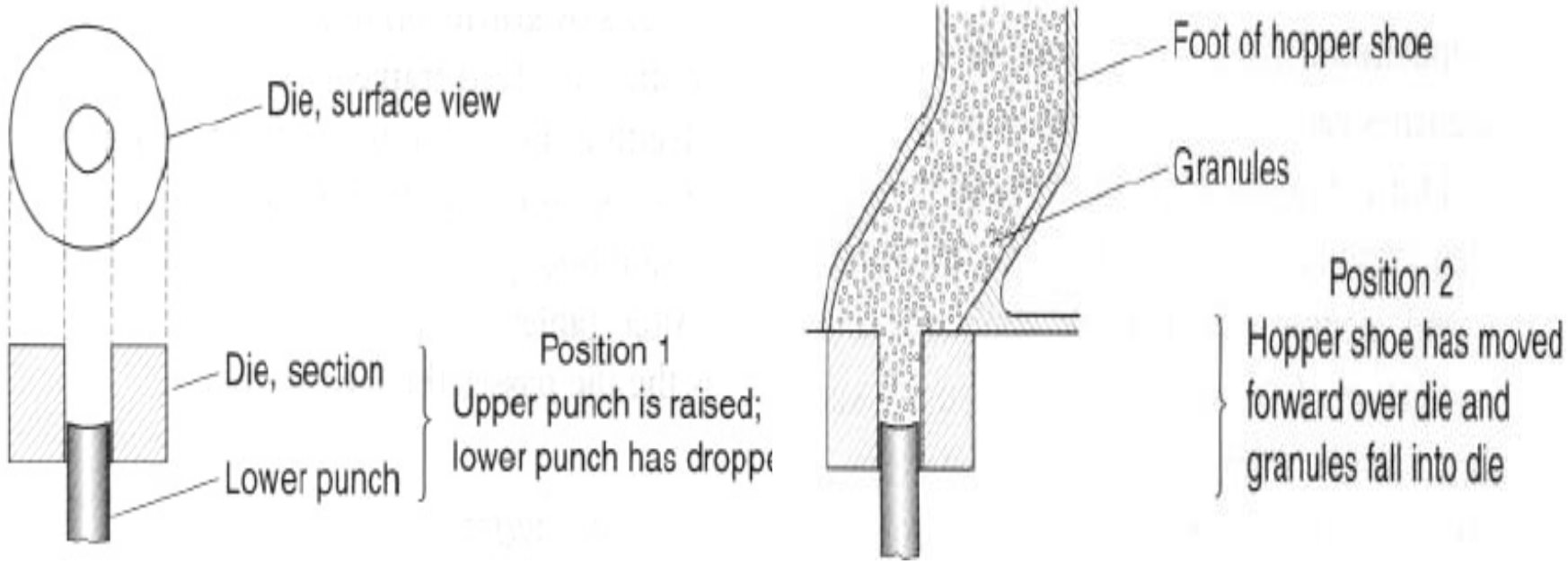

Fig. Filling stage in tablet compression process

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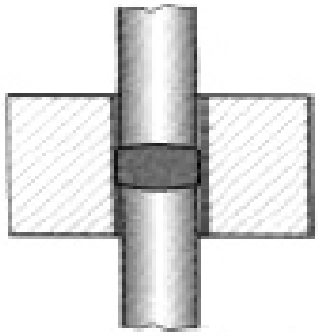
- The die is filled by a **volumetric** process:
  - The volume is determined by the **depth** to which the lower punch descends in the die.
  - Unless this volume is filled **reproducibly** on each occasion, then the mass of the tablet will vary, and with it the drug content of each tablet



Stage 2: Compression

- The upper punch descends, and its tip enters the die, confining the particles
- The distance separating the punch faces decreases, either by:
  - Movement of the upper punch alone (as in **excentric** presses)

    or

  - Movement of both punches (as happens in **rotary** presses)

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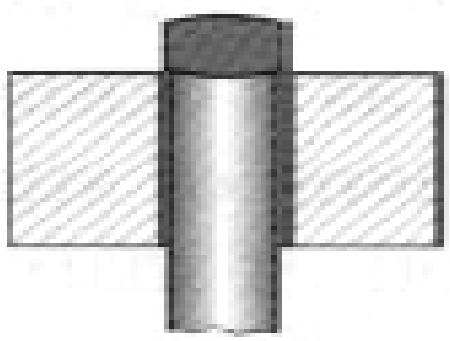
- The porosity of the contents of the die is progressively reduced,
- And, the particles are forced into very closer proximity to each other.
- Once the particles are close enough together, interparticulate forces then cause the individual particles to aggregate, forming a tablet.

Stage 3: Ejection

- The upper punch is **withdrawn** from the die,
- As the upper punch leaves the die, the lower punch moves **upwards**, pushing the tablet before it.



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- During the compression stage, the particles are forced into intimate contact with the interior die wall.
  - Attempts to remove the tablet will be opposed by frictional forces, and
  - So, successful ejection demands lack of adhesion between the tablet and the die wall

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- For a particulate solid to be successfully transformed into tablets, three key properties need to be present:

  ✓Good particle **flow**,

  ✓The ability of the particles to **cohere** under the influence of a compressing force,

  ✓The ability of the tablet to be **ejected** from the die.

Tablet presses

- There are two types of press in common use during tablet production:
  - The excentric press has one die and one pair of punches.
  - The rotary press has a larger number of dies which are fitted with their corresponding punches into a rotating turret

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A. Single-punch press (Excentric press)

- The powder is held in a hopper,
- Hopper is connected to a hopper shoe located at the die table,
- Hopper shoe moves to and from over die,
  - When the hopper shoe is located over the die, the powder is fed into the die by gravity.
  - When the hopper shoe is located beside the die, the upper punch descends and the powder is compressed.

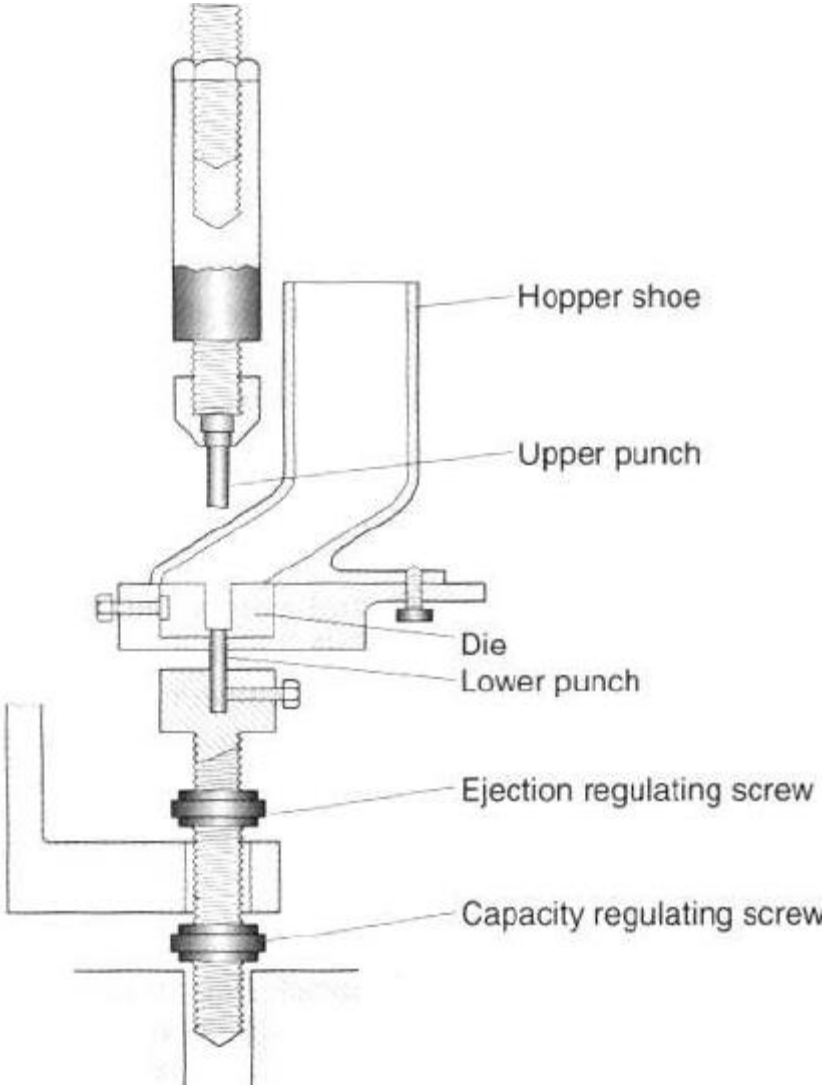
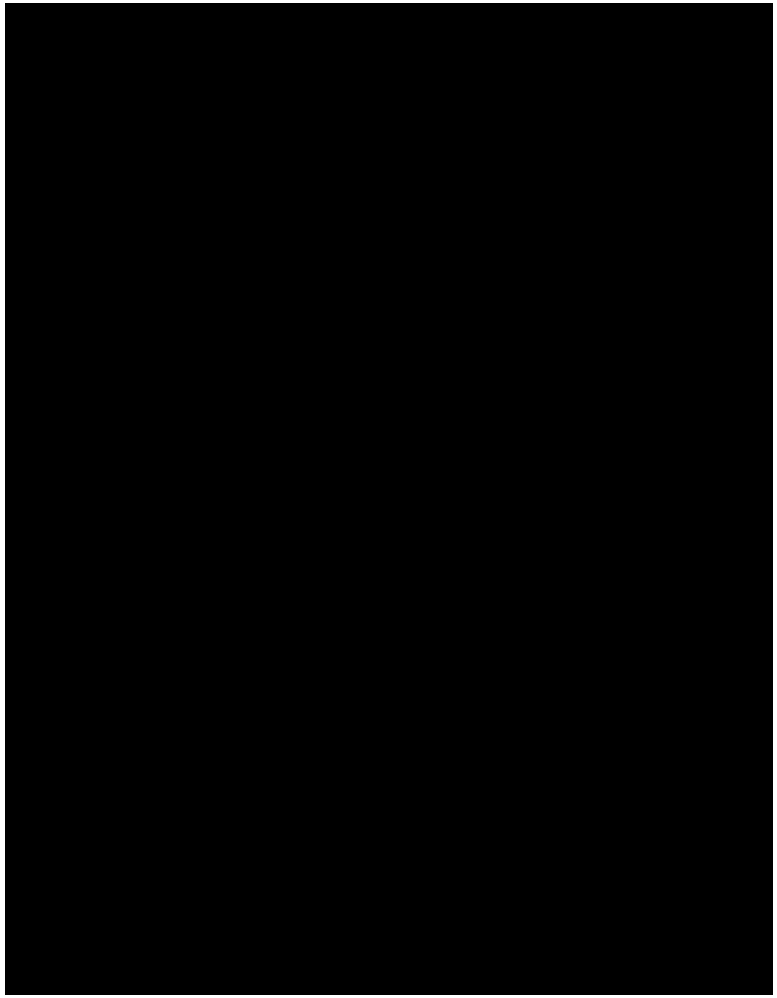


Fig. Single-punch tablet press

- The lower punch is stationary during compression,
- Pressure is applied by the upper punch and controlled by the upper punch displacement.
- After ejection of the tablet pushed away by the hopper shoe as it moves back to die for the next tablet.



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B. Rotary press

- The head of the tablet machine that holds the upper punches, dies, and lower punches in the place **rotates**.

- As the head rotates, the punches are **guided** up and down by fixed cam tracks, which control the sequence of filling, compression and ejection.

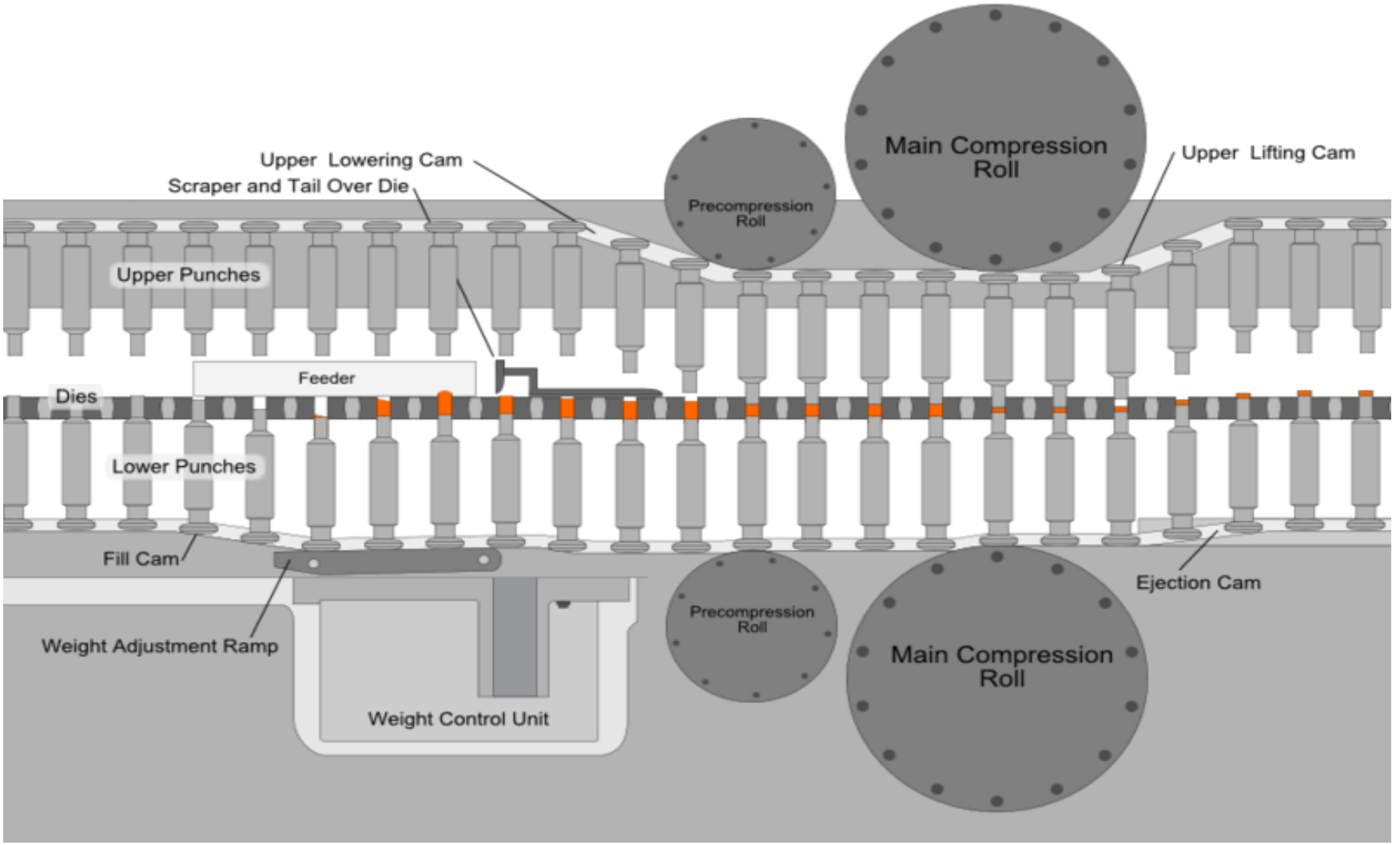

Fig. Rotary tablet press.

- Output of tablet machine regulated by three basic characteristics of its design:
  - Number of tooling sets
  - Number of compression station
  - Rotational speed of the press

- Compression machine **tooling**
  - Tooling set must satisfy dosage requirement
  - The size and shape of tablet as well as certain identification marking are determined by the compression machine tooling
  - Each tooling set consists of die, upper and lower punches
  - Small rotary press punches has 60 or more dies and 60 or more pairs of punches

- **Auxiliary** Equipments
  - Are equipments which increase the efficiency of a tablet compression operation include:
    - Mechanized feeders
    - Granulation level sensors
    - Devices for continuous monitoring of tablet weight
    - Tablet deduster

- Mechanized feeders
  - To force granulation into the dies
  - To prevent weight variation due to improper filing of a poorly flowing granulation
  - Means for replenishing (filing of hopper at constant interval; mechanized equipment to load granulation into the hoppers)
- Granulation level sensors
  - To stop the press automatically when the granules level drops to a critical level in the hoper

- Devices for continuous monitoring of tablet weight
  - Monitor the force of each compression station, which correlated with tablet weight
  - The monitories are capable initiating corrective actions
  - Altering the amounts of die fill to maintenance a fixed force
  - Ejecting tablets that are out of specifications
  - Counting
  - Documenting the machine operation throughout the run
- Tablet deduster
  - Tablets coming off a tablet machine bear excess powder and are run through a tablet deduster to remove the excess powder.

Methods of tablet production

- Two methods of tablet manufacturing

1. Tablet manufacture by **Granulation**
    - Tablet manufacture by Dry Granulation
    - Tablet manufacture by Wet Granulation
2. Tablet manufacture by **Direct compression**

Tablet Manufacture by Granulation

- Reasons for granulation:

1. To prevent segregation,
2. To improve the flow properties,
3. To improve the compaction characteristics,
4. To increase the bulk density,
5. To reduce dusting of powders,
6. To reduce cake formation in hygroscopic powders,
7. Granules occupy less volume per unit weight

- Reasons for granulation:

1. To prevent segregation of the constituents of the powder mix

    - An ideal granulation will contain all the constituents of the mix in the correct proportion in each granule, and segregation of the ingredients

2. To improve the flow properties of the mix

- Many powders, because of their small size, irregular shape or surface characteristics, are cohesive and do not flow well

- Granules produced from such a cohesive system will be larger and more isodiametric sphere

  - Contributing to improved flow properties

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3. To improve the compaction characteristics of the mix

- Granules are often more easily compacted and produce stronger tablets than powder of same substance.
  - This is associated with the distribution of the adhesive within the granule and is a function of the granulation method
  - Often solute migration occurring during the post granulation drying stage results in a binder-rich outer layer to the granules
  - Direct binder-binder bonding

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4. To increase the bulk density of the powder mixture and thus ensure that the required volume of powder can he filled into the die

5. The granulation of toxic materials will reduce the hazard associated with the generation of toxic dust

6. Materials which are slightly hygroscopic may adhere and form a cake if stored as a powder.

7. Granules occupy less volume per unit weight

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Tablet Manufacture by Wet Granulation

- Particles of active ingredient, with a diluent if necessary, are stuck together using an adhesive (usually being water-based).

- The result is a granular product which flows more readily and has an improved ability to cohere during compression.

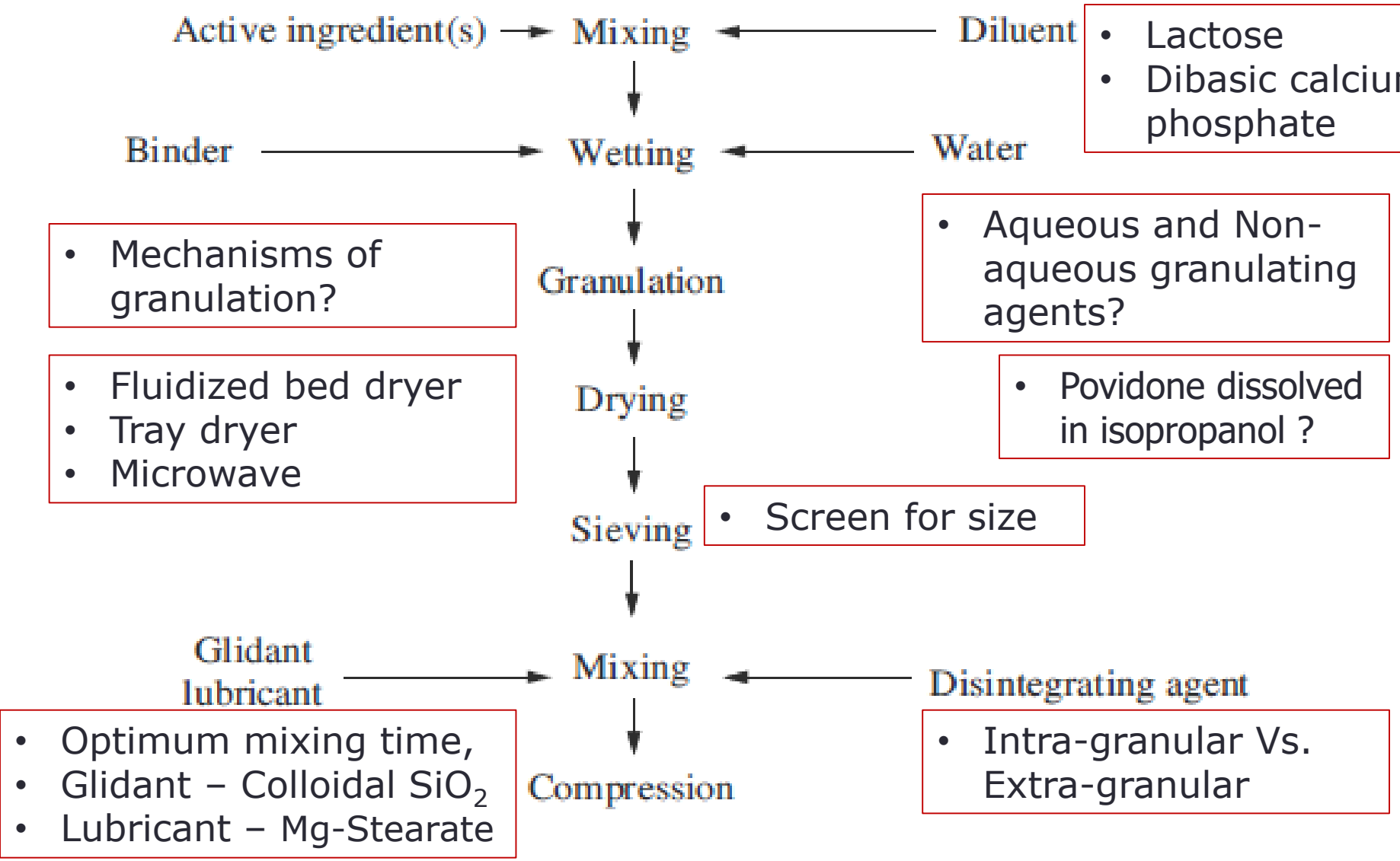

Fig. Stages in tablet manufacture by wet granulation.

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a) Dry mixing stage

- The first stage in the wet granulation process,
- The active component is mixed with a diluent,
- Lactose is by far the most frequently used diluent for solid dosage forms.
- The second most commonly used diluent in the wet granulation process is dibasic calcium phosphate.

- The purpose of the mixing stage is to ensure that the powder blend and hence the resulting tablets are homogeneous in content

- Powder particles do not mix spontaneously but remain in their relative positions

  - Energy must be put into the system

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b) Granulation

- The underlying process of size enlargement in wet granulation is achieved by different mechanisms:
  - Firstly, adjacent solid particles may be stuck together using an adhesive (binders or granulating agents),
  - Secondly, dissolution of the solid in the granulating liquid can occur, followed by evaporation of the liquid phase.
    - This result in the deposition of dissolved material on particle surfaces, forming so-called crystal bridges.

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- If the API is unstable in the presence of water, then a granulation process using non-aqueous liquids can be used.
  - The usual granulating system in such cases is povidone dissolved in isopropanol.
  - The extra costs and environmental problems limit the use of non-aqueous granulation.

Granulating apparatus

- ***Shear granulator***
  - To homogeneously incorporate an adhesive and viscous liquid such as starch paste into a mass of dry powder to form agglomerates.
  - Considerable shearing force needs to be exerted.
  - The mixed solids are loaded into the bowl of the mixer, and the liquid added with agitation.
  - The damp solid is then forced through a relatively coarse screen often by means of oscillating bars, to give discrete granules.

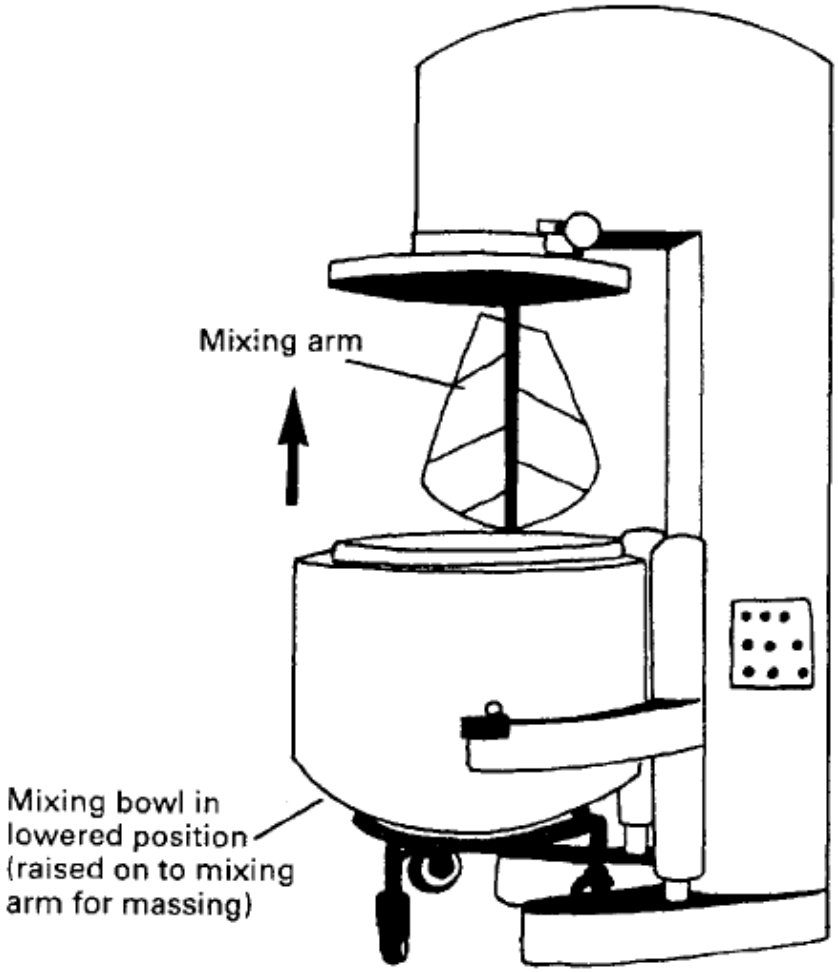

Fig. Schematic representation of Shear granulator

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- ***High-speed mixer granulators***
  - Have agitator and chopping blades,
  - Enable mixing, wet massing, and granulation to take place in the same piece of apparatus.
  - The granulation process takes place extremely rapidly,

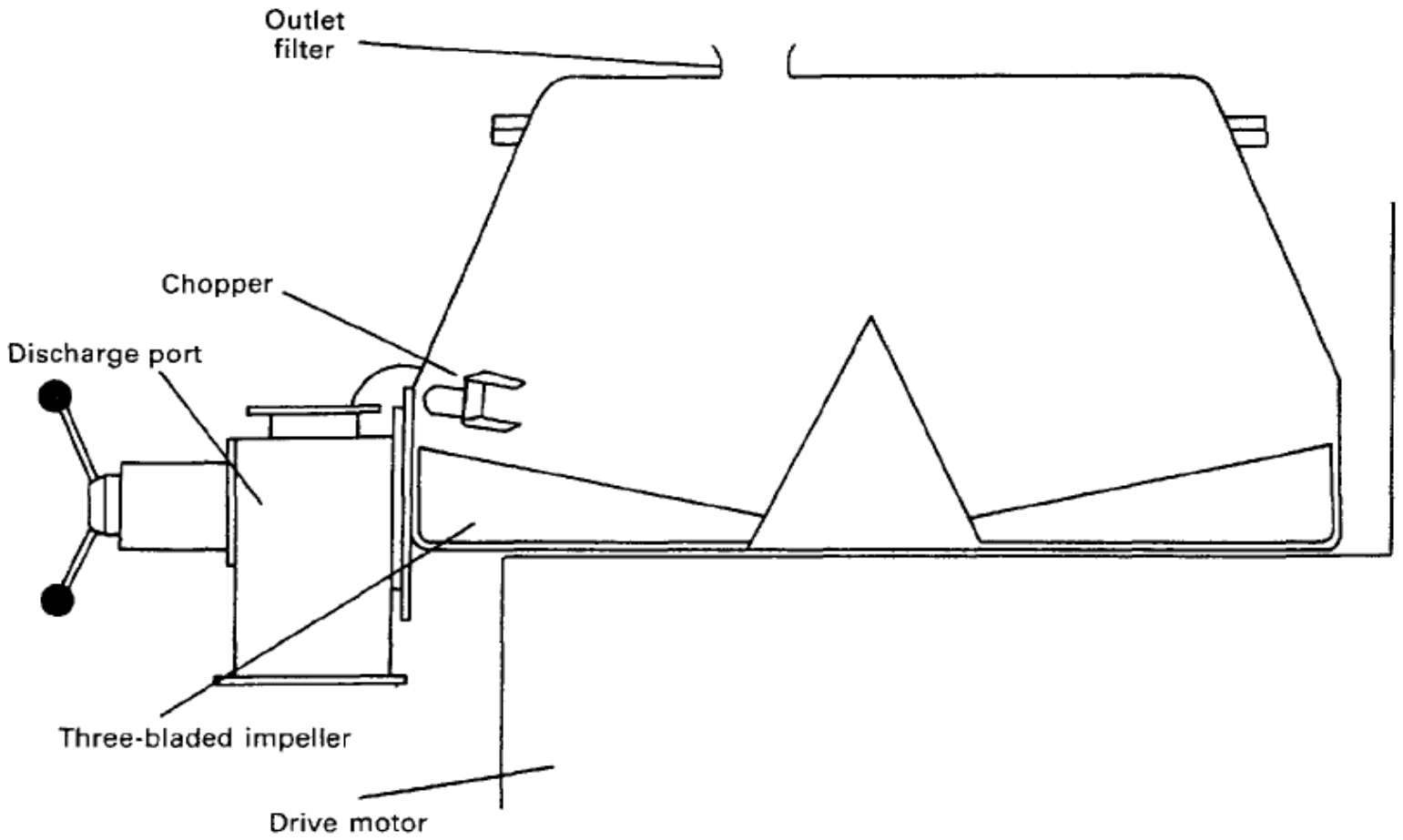

Fig. Schematic representation of high-speed mixer granulator.

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- ***Fluid-bed granulation***
  - Air is passed into the powder bed from below.
    - This causes the particle, of powder to form a suspension in the air and gives effective mixing
  - The granulating fluid is then sprayed over the particles, which adhere on collision and they are then dried in the heated air stream

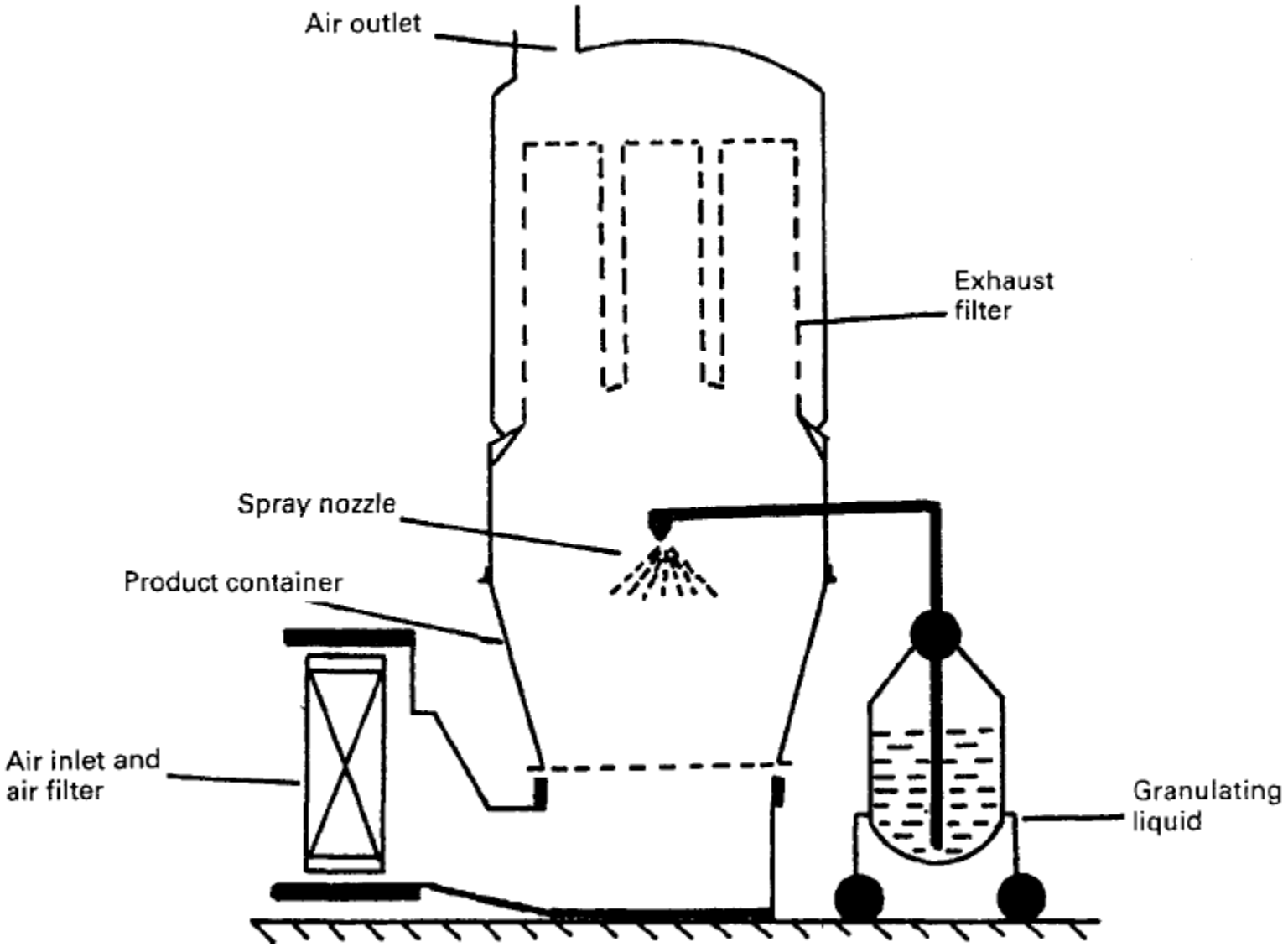

Fig. Schematic representation of fluid-bed granulator.

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c) Drying

- The fluidized bed drier is the most commonly used device for drying tablet granules
  - The air provides an effective means of heat transfer, as well as of removing water vapor.
  - Apparatus based on the fluidized bed principle is available in which mixing, granulation, and drying take place in the same chamber

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- A more traditional means of drying is the tray drier.
  - Hot air flows over a series of shelves on which the wet material is spread.
  - Compared to the fluidized bed drier, the solid–air interface is smaller, and water molecules may have to diffuse through the whole thickness of the solid layer before the evaporative surface is reached.

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- Microwaves are being increasingly employed in the pharmaceutical industry for drying purposes.
  - The incident microwave radiation causes electrons in substances such as water to resonate, which in turn generates heat and causes the water to evaporate.
  - The water vapor is removed under vacuum, and hence the product dries rapidly at a relatively low temperature.

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d) Second mixing stage

- When the drying process is complete, it is likely that the product will have cohered into relatively large masses
  - The dried material is passed through a sieve to break up aggregates and to give a relatively uniformly sized granule.
- A second mixing stage follows in which several important ingredients of the formulation are added.

- Glidant
  - If flow is still not good enough, a glidant can be added to improve flow
  - The most frequently used glidant is colloidal silicon dioxide
    - Act by lodging in the surface irregularities of the granule, forming a more rounded structure and hence reducing interparticulate friction.
    - Colloidal silicon dioxide has the added advantage of acting as a moisture scavenger

- Lubricant
  - When the tablet formulation is compressed, the sides of the tablet are brought into intimate contact with the die wall
    - The tablet must then be ejected from the die, involving the movement of the side of the tablet relative to the die wall
    - Therefore, friction between the tablet and the die wall must be overcome

- A lubricant is a substance that deforms easily when sheared between two surfaces, and hence when interposed between the tablet and the die wall, provides a readily deformable film

- Inadequate lubrication can often be recognized by vertical scratches on the sides of the tablet.

- It may also lead to a build-up of solid on the punch faces, which in turn gives a picking

- Magnesium stearate is by far the most frequently used tablet lubricant, and is extremely effective

- To act as an effective lubricant in a tablet, the lubricant must be dispersed over the surface of the powder particles or granules
  - The more complete this layer, the more effective the lubricant action will be,
  - However, this has two deleterious consequences:
    - The first is that each powder particle presents a hydrophobic and hence water repellent exterior,
    - The second consequence is that direct contact between powder particles is, at least in part, replaced by contact between adjacent hydrocarbon layers

- There is a need to establish a minimum lubricant concentration and an optimum mixing time within which adequate lubrication is achieved without the development of undesirable tablet characteristics

- A mixing time of 2–5 min usually suffices to give adequate lubrication

- The disintegrating agent

  - Tablet formulations often include a disintegrating agent, which when it comes into contact with water, disrupts the tablet structure and leads to fragmentation.

    - A larger surface area is thus exposed to the dissolving fluid and dissolution is facilitated.

- The disintegrating agent may be mixed with other powders prior to wetting with the granulating fluid (intragranular) or at the second mixing stage (extragranular), or both
  - Extragranular disintegrating agents caused the tablet to disintegrate quicker
  - Intragranular disintegrants not only broke down the tablet but also the constituent granules, giving a finer product

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Tablet Manufacture by Dry Granulation

- Wet granulation method of tablet manufacture suffers from several disadvantages
  - Water is the usual granulating fluid, and this exposes tablet ingredients to the danger of **hydrolysis**.
  - The granulating fluid has to be removed, usually by **heating**.
    - Incur energy costs,
    - Elevated T will accelerate any hydrolytic reaction

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- Dry granulation is an alternative method
  - The components of the formulation are compressed in the dry state
  - If sufficient bonding strength cannot be achieved by compression alone, a binder is added, also in the dry state

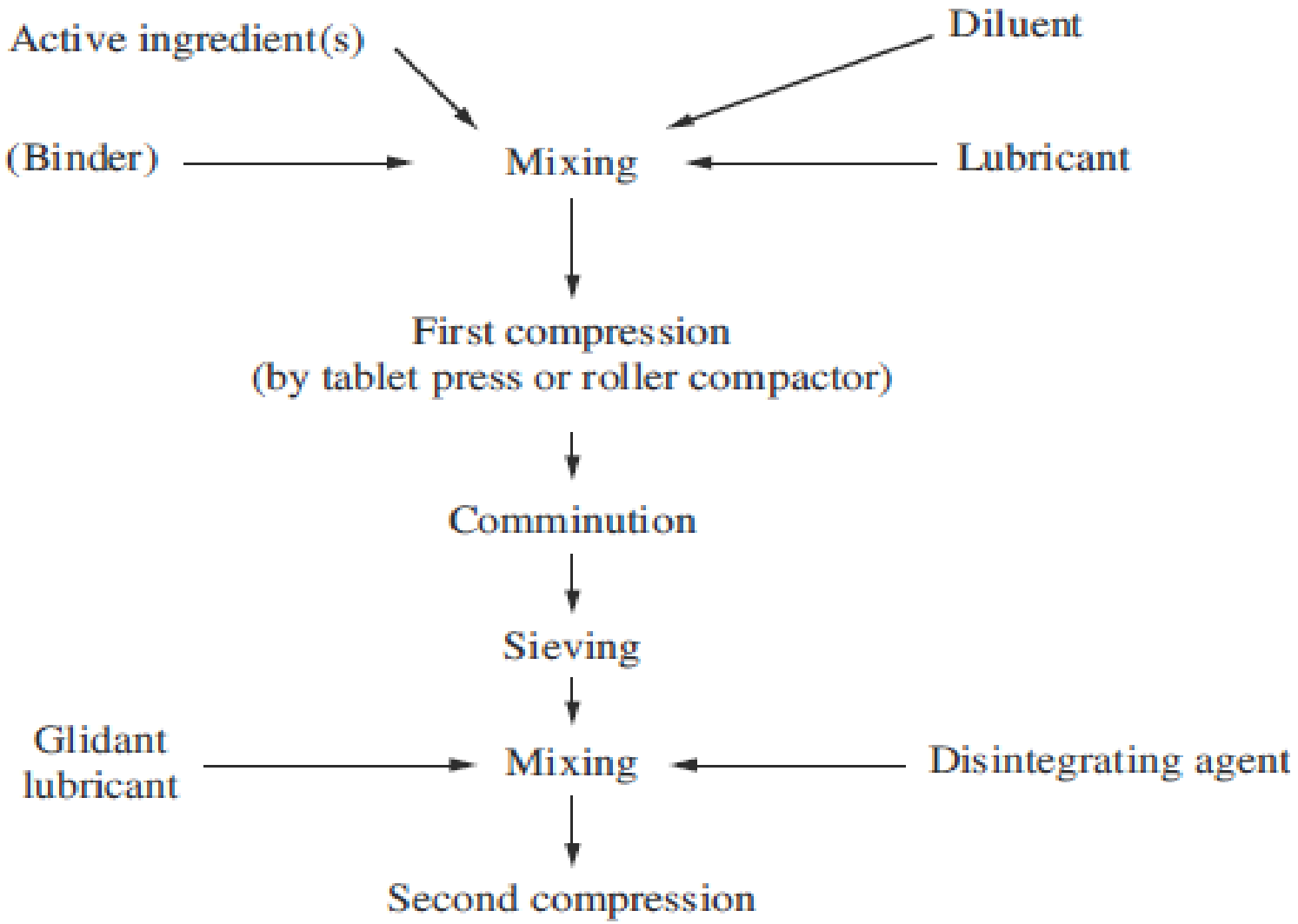

Fig. Stages in tablet manufacture by dry granulation.

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- The initial compression stage can take place by one of two methods.
  - The first uses a conventional tablet press, a process often referred to as "**slugging**."
  - A second method of compression is to use a **roller compactor**.
    - Powder mixture is passed between two contra-rotating cylindrical rollers to form a cake.

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Tablet Manufacture by Direct Compression

- Granulation would be unnecessary:
  - If a major component of the formulation already possesses the necessary degree of flowability and compressibility,.
- The key component here is the diluent,
  - Which must possess required properties for direct compression.

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- Advantages of Direct compression:
  - Reduced capital (equipment and material costs),
  - Labor and energy costs,
  - Avoidance of water for granulation,
  - Avoid heat for drying.

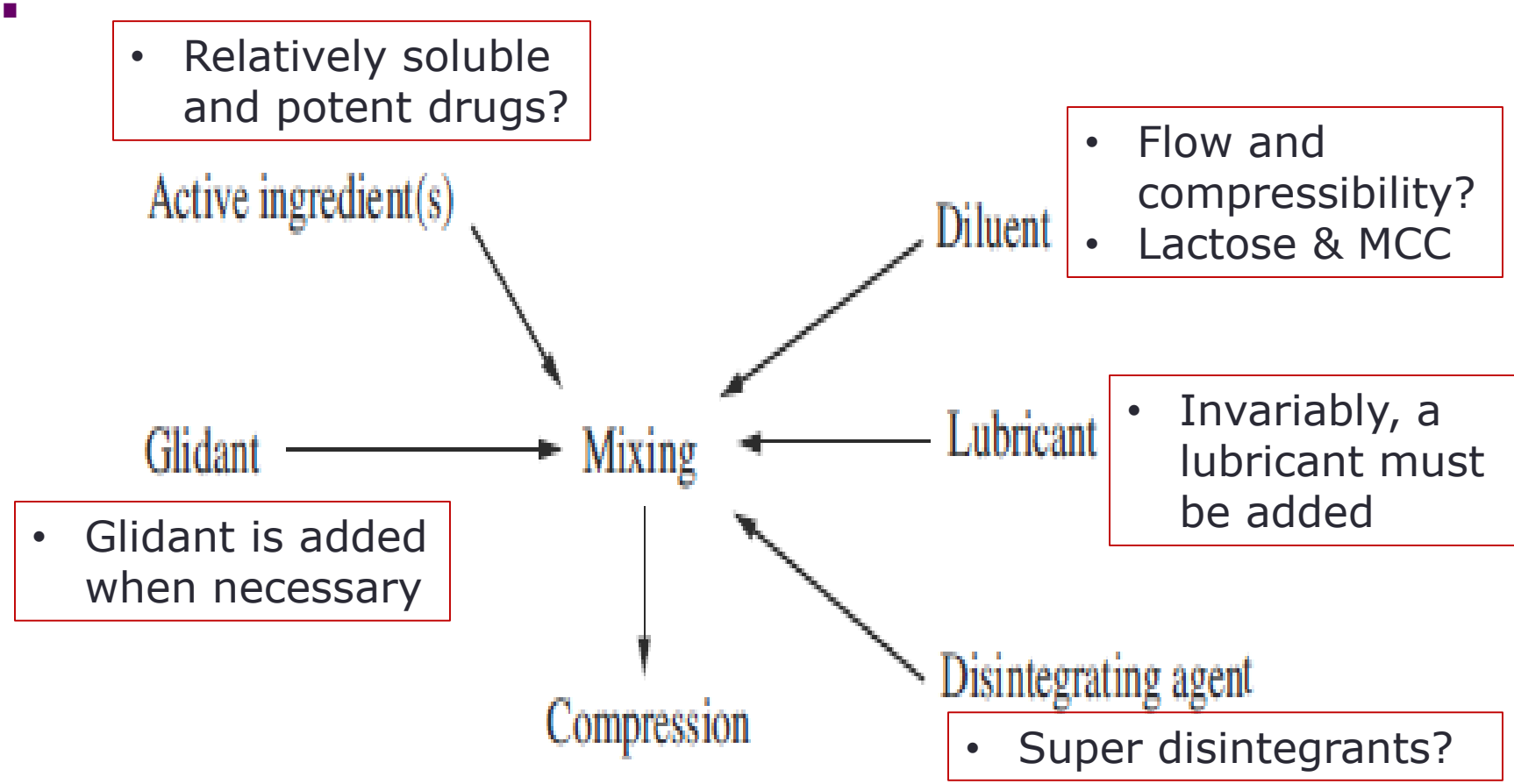

Fig. Stages in tablet manufacture by direct compression.

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- The ingredients are mixed together and then compressed
  - Almost invariably a lubricant must be added, and a glidant and a disintegrating agent included when necessary
  - The process does not involve the use of a liquid, and hence a drying stage with its attendant energy costs is avoided
- The two most frequently used direct compression diluents are spray-dried lactose and microcrystalline cellulose

- Direct compression mainly used for two types of drugs
  - Relatively soluble drugs which can be processed as coarse particles (to ensure good flowability),
  - Relatively potent drugs which are present in a few mgs in each tablet and can be mixed with relatively coarse excipient particles.

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- Direct compression can offer significant savings in energy, equipment, and material handling costs.
  - Against this must be set higher ingredient costs, since direct compression diluents are more expensive than other diluents
- An even coloring of tablets can be difficult to achieve with a colorants in dry particulate form

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- In a direct compression formulation:
  - The components can behave as individual particles,
    - There might be a possibility of **segregation** after mixing and prior to compression
  - The reduction in **dust formation** brought about by granulation cannot occur in direct compression

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Problems in tableting and troubleshooting

1. Capping and lamination

- **Capping** – partial or complete separation of the top or bottom crowns of a tablet from the main body of the tablet.
- **Lamination** – separation of a tablet into two or more distinct layers.
- Capping and lamination can exist immediately up on ejection or hours or weeks after ejection.

- Causes for capping and lamination:
  - Entrapment of air during compression,
  - The deformational properties of the formulation during and immediately following compression,
    - Pre compression, slowing tabletting rate and reducing the final compression pressure.
  - Granulation that are light or contain large amount of powder
    - Reduce or remove powder by sieving

- Granulation may be too dry,
- Deep concave punch,
- Carelessness in setting up the press,
- Develop of wears in area of compression dies,
- Tablet shape,
- Granulation may contain lower amount of binders,
- Increase in CF or decrease in CF.

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2. *Picking and sticking*

- **Picking** ~ when a small amount of material from a tablet is sticking to and being removed off from the tablet surface by a punch face

- Picking is due to:

  - Engraving or embossing letters

  - The granular material is improperly dried

  - Improperly lubricated granules

- Solution:
  - Dry the granules properly
  - Increase lubricant
  - Compress at room temperature
  - Use flat punch face and polish faces
  - Use high melting substances
  - Design lettering as large as possible

- **Sticking** ~ Refers to the tablet material adhering to the die wall
  - Due to improperly dried or improperly lubricated granules
  - Solution:
    - Increase or change lubricant
    - Dry granules properly

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3. Mottling

- Non-uniform distribution of color on a tablet
- Due to:
  - Colored drugs, whose color differs form the color of excipients
  - Drug whose degradation products are colored
  - Use of poor colorant
  - Migration of color during mixing or drying
  - Poor mixing of drug and excipients

- Solution:
  - Use of appropriate colorants
  - Mix properly
  - Reducing drying temperature
  - Grinding to a smaller particle size
  - Changing the solvent system

4. Weight variation

- The weight of a tablet being compressed is determined by the amount of granules/powder in the die prior to compression
  - Any thing that can alter the die filling process can alter tablet weight and result in weight variation

- Possible reasons for **weight variation**:

1. Variation in granule size and size distribution, (Solution?)
2. Poor flow, (Solution: Glidants? Inducing feeder? Vibration?)
3. Poor mixing,
4. Punch variation (lower punches are of unequal length),

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- Possible reasons for **weight variation**:

a) Variation in granule size and size distribution before compression

- Variation in ratio of small to large granules and in Magnitude of difference between granule sizes influence how void space between particles is filled

- Different proportions of large and small particles may change the weight of fill in each die.

- Solution: maintain uniform size distribution

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b) Poor flow

- The die fill process is based on a continuous and uniform flow of granulation from the hopper through the feed frame.
- Problems:
  - Dies are incompletely filled when the granulation does not flow readily and machine speed is in excess of the granulation flow capabilities

- Possible solution:
  - Addition of glidant or an increase in the amount already present
  - Use of induced die feeders – mechanically force granulation down into die cavities.
  - Attaching vibrators to the hopper sides to induce the granulation flow

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c) Poor mixing

- If the glidants are not well distributed, flow of particle impaired and the granule do not move efficiently into the dies.
- Solution: optimum mixing times

d) Punch variation

- When lower punches are of unequal length, the volumetric fill in each die varies

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5. Hardness variation

- Depending on:
  - The weight of material and
  - The space between the upper and lower punches at the movement of compression

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Quality evaluation

A. General appearance

- Overall elegance, batch to batch uniformity and tablet to tablet uniformity.

- Control size, shape, color, presence or absence of an odor, taste, surface texture, physical consistency, legibility of any identifying marking.

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B. *Uniformity of content of API*

- In practice, small variations between individual preparations are accepted,
- Limits for such variations are defined as standards in pharmacopoeias,
- For tablets, uniformity of dose or dose variation is tested in two separate tests:

a) Uniformity of weight

b) Uniformity of active ingredient

- The test for uniformity of weight:
  - Take sample of 20 tablets from a batch,
  - Determine their individual weights,
  - Calculate the average weight,
  - Then, meet the **USP** test if no more than 2 tablets are outside the percentage limit and if no tablet differs by more than 2 times the percentage limit.

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- If the drug substance forms the greater part of the tablet mass, any weight variation obviously reflects variations in the content of active ingredient.

- In the case of potent drugs, the correlation between tablet weight and amount of active ingredient can be poor.

  - The test for weight variation must be combined with a test for variation in content of the drug substance.

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- The test for content uniformity:
  - 30 tablets are randomly taken,
  - 10 of them are assayed individually,
  - 9 of the 10 tablets must contain NLT 85% or NMT 115% of the labeled drug content,
  - The 10th tablet must contain NLT 75% or NMT 125% of the labeled content,
  - If these conditions are not meet, the tablets remaining from the 30 must be assayed individually and non of them outside of the 85% to 115% range.

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C. Disintegration

- The test is carried out by agitating a given number of tablets in medium (water, simulated gastric fluid or simulated intestinal fluid) at a defined temperature, and the time to reach the end-point of the test is recorded.

- The preparation complies with the test if the time to reach this end-point is below a given limit.

- The end-point of the test is the point at which all visible parts of the tablets have been eliminated from a set of tubes in which the tablets have been held during agitation.

- A disintegration apparatus consists normally of six tubes.
- Before disintegration testing, one tablet is placed in each tube and a plastic disc is placed upon it.
- The tubes are placed in beaker containing medium and this placed a water bath and raised and lowered at a constant frequency in the water.

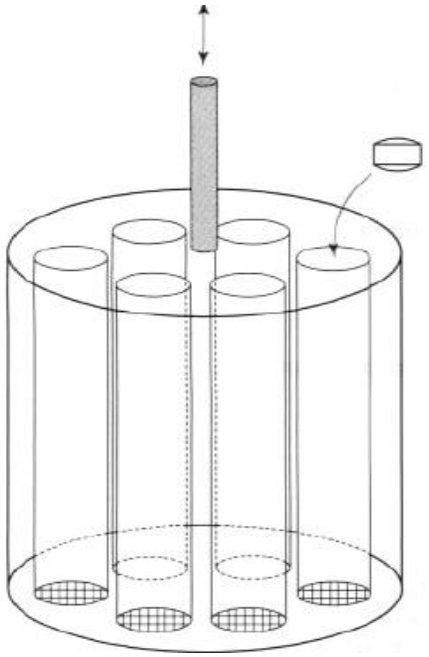

Fig. Disintegration apparatus.

- Tablets remain 2.5cm below the surface of the liquid on their upward movement and descend not closer than 2.5cm from the bottom of the beaker.
- Tablets move up and down through a distance of 5 to 6 cm at a frequency of 28 to 32 cycles per minute.
- The tablets must disintegrate, and all particles must pass through the 10 mesh screen in time specified
  - Many tablet's disintegration time = 15 minute
- Enteric coated tablets should show no evidence of disintegration after 1 hour in simulated gastric fluid

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D. *Dissolution*

- Is the most important way to study, under *in vitro* conditions, the release of a drug from a solid dosage form, and thus represents an important tool to assess factors that affect the bioavailability of a drug from a solid preparation.

- During a dissolution test the cumulative amount of drug that passes into solution is studied as a function of time

- Periodically sample 5ml and replace 5ml of dissolution medium to maintain the volume.
    - Sampling taken up to 60min for conventional tablet and 8-12 hrs for sustain release tablets.
- Its concentration is determined by using UV or HPLC.

- Dissolution studies are carried out for several reasons:
  - To evaluate the potential effect of formulation and process variables on the bioavailability of a drug
  - To ensure that preparations comply with product specifications
  - To indicate the performance of the preparation under in vivo conditions

- A number of official and unofficial methods exist for dissolution testing
- The main test methods are based on forced movement of the dissolution medium and can be classified into two groups:
  - Stirred-vessel methods and
  - Continuous-flow methods

1. Stirred-vessel methods

- The most important stirred-vessel methods are the **paddle** method and the rotating-**basket** method
- Both use the same type of vessel, which is filled with a dissolution medium of controlled volume and temperature
- In the paddle method, the tablet is placed in the vessel and the dissolution medium is agitated by a rotating paddle

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- In the rotating-basket method, the tablet is placed in a small basket formed from a screen.
- This is then immersed in the dissolution medium and rotated at a given speed

Fig. Dissolution medium

Paddle

Basket

2. Continuous-flow methods

- The preparation is held within a flow cell, through which the dissolution medium is pumped at a controlled rate from a large reservoir
- The liquid which has passed the flow cell is collected for analysis of drug content
- The continuous- flow cell method may have advantages over stirred-vessel methods

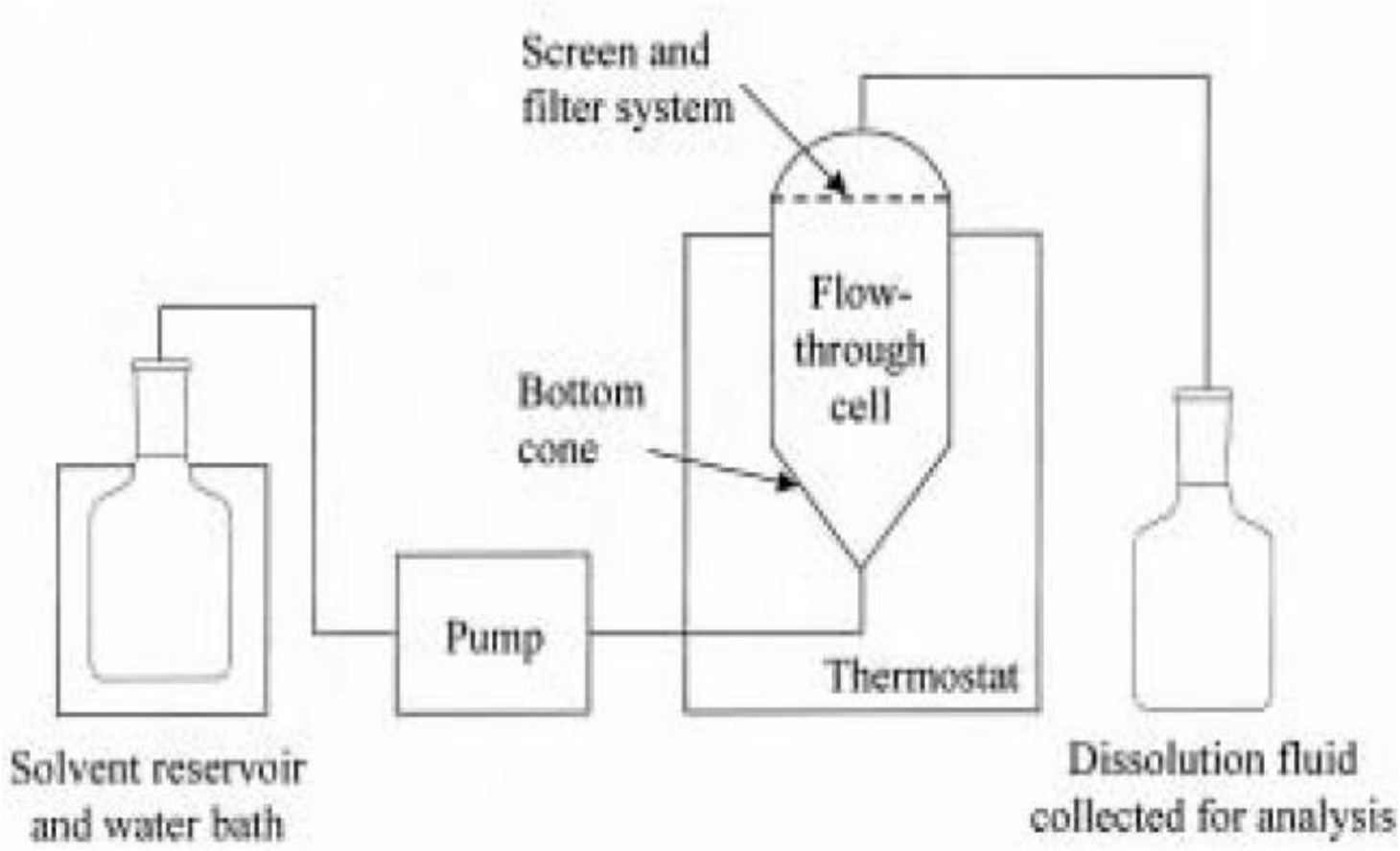

Fig. Schematic representation of continuous- flow cell method

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- The composition of the dissolution medium might vary between different test situations.
  - In many cases a medium that shows a closer resemblance to GI fluid.
  - In such media the pH and ionic strength can be controlled, and surface-active agents might be added to affect the surface tension of the liquid and the solubility of the drug.
  - Such fluids are often referred to as simulated gastric or intestinal fluids.

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E. Mechanical strength

- The mechanical strength of a tablet is associated with the resistance of the tablet towards fracturing and attrition
- An acceptable tablet must remain intact during handling in production and administration

- Mechanical strength testing is carried out for several reasons:
  - To assess the importance of formulation and production variables for the resistance of a tablet towards fracturing and attrition during formulation work, process design and scaling up,
  - To control the quality of tablets during production,
  - To characterize the fundamental mechanical properties of materials used in tablet formulation.

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- Methods for strength testing can be subcategorized into two main groups:

a) Attrition-resistance methods

b) Fracture-resistance methods

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a) Attrition-resistance methods

- The idea behind attrition resistance methods is to mimic the kind of forces to which a tablet is subjected during handling between its production and its administration.
- These are also referred to as **friability tests**
- Friable tablet is one that is prone to erode mechanically during handling.

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- In attrition resistance testing 10 tablets placed in plastic chamber that revolves at 25 rpm,
- Dropping the tablets a distance of 6 inches with each revolution,
- Operation for 100 revolution (4 minutes),
- Tables then dusted and reweighed,
- Weight loss of less than 1 % during a friability test is required.
- In addition, the tablets should not show capping or cracking during such testing.

Fig. Friability taster.

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b) Fracture-resistance methods (hardness test)

- Analysis of the fracture resistance of tablets involves the application of a load on the tablet and the determination of the force needed to fracture or break the tablet along its diameter
- Type of load applied can be compression, pulling or twisting.
- In the diametric compression testing, the tablet is placed against a platen and the load is applied along its diameter by a movable platen.

- The tablet fails ideally along its diameter in a single fracture into two pieces of similar size , and the fracture force is recorded
  - The force is crushing or breaking strength of the tablet

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- The force needed to fracture a tablet depends on the tablet's dimensions
  - An ideal test, however, should allow comparison between tablets of different sizes or even shapes
- This can be accomplished by assessing the strength of the tablet, i.e. the force needed to fracture the tablet per unit fracture area

- Tensile strength test is the indirect diametral compression test.
- If the tablet fails in a tensile fracture mode, for a cylindrical flat faced tablet the tensile strength can be calculated as:

$$\sigma = \frac{2.\mathrm{F}}{\pi.D.T}$$

- where F is the force needed to fracture the tablet and D and T are the diameter and the thickness of tablet

- An alternative procedure to measure the tensile strength of a tablet is to directly pull the tablet apart by the application of stresses along its main axes until fracture occurs, i.e. a direct axial tensile test

- The use of this method is primarily to detect weaknesses in the tablet in the axial direction, which is an indication of capping or lamination tendencies in the tablet